

In re Application of:

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Serial No. 10/791,370

Filed: March 1, 2004

For: DELIVERY SYSTEM AND METHOD

Art Unit: 3767

Examiner: Witczak, Catherine

Atty Docket: 0109/0035

## EXPEDITED PROCEDURE

## 37 CFR 1.116 AMENDMENT AFTER FINAL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is a response to the Office Action dated July 22, 2010. Please amend the above-identified application as follows.

Amend claim 1.

**Amendments to the Claims**

1. (Currently Amended) An implantable system for delivering fluid to a body including:  
a flexible first catheter;  
a flexible second catheter having an inner diameter sized to receive the first catheter, where one end of the first catheter is configured to be received within one end of the second catheter, wherein when the first and second catheters are connected, a portion of the first catheter is fitted within a portion of the second catheter to form the  
~~second catheter receives the first catheter along~~ an overlap area wherein each of the first and second catheters have constant wall thickness in the overlap area;  
a collar with a first opening configured to encircle the first catheter and a second opening configured to encircle the second catheter, wherein the first opening is smaller than the second opening, wherein the collar is configured to surround at least a first portion of the overlap area of the first and second catheters; and  
a clamp for applying a radially inward force to ~~the~~ at least the portion of the collar that surrounds the overlap area to hold the first and second catheters together, ~~wherein the clamp encircles at least a portion of the overlap area.~~
2. (Original) The system of claim 1 further comprising an access device configured to establish fluid communication with the second catheter, the access device comprising:  
a reservoir having an open top and a closed bottom,  
a pierceable and resealable septum received in the open top, and an outlet tube in fluid communication with the reservoir, wherein the outlet tube is configured to be received within one end of the second catheter.
3. (Original) The system of claim 1 wherein the clamp moves between a first open position and a second locked position, wherein in the open position the clamp can receive an end of the second catheter and wherein in the closed position the clamp applies the radially inward force to the overlap area, wherein the clamp locks into the closed position.

4. (Original) The system of claim 3 wherein the clamp includes interlocking teeth that maintain the clamp in the closed position.
5. (Original) The system of claim 1 wherein the clamp comprises:
  - a pair of spaced jaws including a first jaw and a second jaw, the first jaw including teeth; and
  - a tongue configured to be inserted between the spaced jaws when the clamp is in the closed position, the tongue including teeth to mesh with the teeth on the first jaw.
6. (Original) The system of claim 1 wherein the collar includes a recessed area for receiving the clamp.
7. (Original) The system of claim 1 wherein the collar defines a distal cavity adjacent to the first opening and a proximal cavity adjacent to the second opening, wherein the distal and proximal cavities are cylindrical cavities, wherein the distal hollow cavity has a diameter smaller than a diameter of the proximal cavity.
8. (Original) The system of claim 1 wherein the collar defines a proximal cavity adjacent to the second opening and encircled by the clamp, wherein the first portion of the overlap area is positioned within the proximal cavity, the connector further comprising a collet within the proximal cavity, wherein the collet is configured to surround at least the first portion of the overlap area of the first and second catheter, wherein the collet is more rigid than both the first and second catheters, wherein the collet further surrounds a portion of the first catheter that does not overlap with the second catheter.
9. (Original) The system of claim 8, wherein the collet comprises: a ring portion encircling an open passage; and
  - four panels extending from the ring portion, the four panels defining four open areas between the four panels.

10. (Original) The system of claim 9, wherein the first and second openings of the collar are axially aligned.

11. (Original) The system of claim 10 further comprising a sleeve extending from the first opening, wherein the sleeve is configured to surround the first catheter for a sleeved portion of the first catheter, wherein the sleeve has an outer diameter larger than an outer diameter of the first catheter.

12. (Original) The system of claim 11 wherein the sleeved portion is about two to six inches long.

13. (Original) The system of claim 11 wherein the sleeve outer diameter is at least about 50% larger than the first catheter outer diameter.

14. (Original) The system of claim 13 wherein the sleeve outer diameter is at least about twice as large as the first catheter outer diameter.

15. (Original) The system of claim 11 wherein the sleeve includes a flared lip portion at one end, wherein the lip portion is configured to engage an end wall of the proximal cavity within the collar.

16. (Original) The system of claim 1 further comprising a sleeve extending from the first opening, wherein the sleeve is configured to surround the first catheter for a sleeved portion of the first catheter, wherein the sleeve has an outer diameter larger than an outer diameter of the first catheter.

17. (Original) The system of claim 16 wherein the sleeved portion is about two to six inches long.

18. (Original) The system of claim 17 wherein the sleeve outer diameter is at least about 50% larger than the first catheter outer diameter.

19. (Original) The system of claim 18 wherein the sleeve outer diameter is at least about twice as large as the first catheter outer diameter.

20. (Original) The system of claim 16 wherein the sleeve includes a flared lip portion at one end, wherein the lip portion is configured to engage an end wall of the proximal cavity within the collar.

21. (Withdrawn) A connector for connecting a first catheter and a second catheter, where one end of the first catheter is configured to be received within one end of the second catheter, wherein when the first and second catheters are connected the second catheter receives the first catheter along an overlap area, comprising:

- a collar with a first opening configured to encircle the first catheter and a second opening configured to encircle the second catheter, wherein the first opening is smaller than the second opening, wherein the collar is configured to surround at least a first portion of the overlap area of the second catheter; and

- a clamp for applying a radially inward force to the collar to hold the first and second catheter together, wherein the clamp encircles at least a portion of the overlap area;

- wherein the clamp moves between a first open position and a second locked position wherein in the open position the clamp can receive an end of the second catheter and wherein in the closed position the clamp applies the radially inward force to the overlap area, wherein the clamp locks into the closed position;

- wherein the clamp comprises:

- a pair of spaced jaws including a first jaw and a second jaw, the first jaw including teeth; and

- a tongue configured to be inserted between the spaced jaws when the connector is in a closed position, the tongue including teeth to mesh with the teeth on the first jaw;

- wherein the collar includes a recessed area for receiving the clamp.

22-24. (Canceled)

25. (Withdrawn) The connector of claim 21 wherein the collar defines a proximal cavity adjacent to the second opening and encircled by the clamp, wherein the first portion of the overlap area is positioned within the cavity, the connector further comprising a collet within the cavity, wherein the collet is configured to surround at least the first portion of the overlap area of the first and second catheter, wherein the collet is more rigid than both the first and second catheters, wherein the collet further surrounds a portion of the first catheter that is not within the overlap area.

26. (Withdrawn) The connector of claim 25, wherein the collet comprises:  
a ring portion encircling an open passage; and  
four panels extending from the ring portion, the four panels defining four open areas between the four panels.

27. (Withdrawn) The connector of claim 26, wherein the first and second openings of the collar are axially aligned.

28. (Withdrawn) The connector of claim 21 further comprising a sleeve extending from the first opening, wherein the sleeve is configured to surround the first catheter for a sleeved portion of the first catheter, wherein the sleeve has an outer diameter larger than an outer diameter of the first catheter.

29. (Withdrawn) The connector of claim 28 wherein the sleeved portion is about two to six inches long.

30. (Withdrawn) The connector of claim 28 wherein the sleeve includes a flared lip portion at one end, wherein the lip portion is configured to engage an end wall of the proximal cavity within the collar.

31. (Canceled)

32. (Withdrawn) A connector for connecting a first catheter and a second catheter, where one end of the first catheter is configured to be received within one end of the second catheter, wherein when the first and second catheters are connected the second catheter receives the first catheter along an overlap area, wherein the first catheter is a fluid delivery catheter configured to enter a body lumen at an incision site, the connector comprising:

a collar with a first opening for encircling the first catheter and a second opening for encircling the second catheter, wherein the collar is configured to surround at least a first portion of the overlap area of the second catheter; and

a clamp for applying a radially inward force to the collar to hold the first and second catheter together; and

a flexible sleeve encircled by the first opening of the collar and configured to surround the first catheter for a portion of the length of the first catheter extending from the first opening of the collar, wherein the sleeve has an outer diameter larger than an outer diameter of the first catheter, wherein the sleeve is configured to extend along the first catheter into the incision site; wherein the sleeve includes a flared lip portion at one end wherein the lip portion is configured to engage an end wall of the proximal cavity within the collar.

33. (Withdrawn) The connector of claim 32 wherein the sleeve is at least about 2 inches long.

34. (Withdrawn) The connector of claim 32 wherein the sleeve outer diameter is at least about 50% larger than the first catheter outer diameter.

35. (Canceled)

36. (Withdrawn) An implantable system for delivering fluid to a body including:

a flexible first catheter;

a flexible second catheter, where one end of the first catheter is configured to be received within one end of the second catheter, wherein when the first and second catheters are connected the second catheter receives the first catheter along an overlap area, wherein each of the first and second catheters have constant wall thickness in the overlap area;

an access device configured to be connected to the second catheter, the access device comprising a reservoir having an open top and a closed bottom, a peaceable and resealable septum received in the open top, and an outlet tube in fluid communication with the reservoir, wherein the outlet tube is configured to be received within one end of the second catheter,

a collar with a first opening configured to encircle the first catheter and a second opening configured to encircle the second catheter, wherein the first opening is smaller than the second opening, wherein the collar is configured to surround at least a first portion of the overlap area of the first and second catheters;

a clamp for applying a radially inward force to the collar to hold the first and second catheters together, wherein the clamp encircles at least a portion of the overlap area, wherein the clamp moves between a first open position and a second locked position, wherein in the open position the clamp can receive an end of the second catheter and wherein in the closed position the clamp applies the radially inward force to the overlap area, wherein the clamp locks into the closed position, wherein the clamp includes interlocking teeth that maintain the clamp in the closed position; and

a sleeve extending from the first opening, wherein the sleeve is configured to surround the first catheter for a sleeved portion of the first catheter, wherein the sleeve has an outer diameter larger than an outer diameter of the first catheter.

37. (Withdrawn) The system of claim 36 wherein the clamp comprises:

a pair of spaced jaws including a first jaw and a second jaw, the first jaw including teeth; and



a tongue configured to be inserted between the spaced jaws when the clamp is in the closed position, the tongue including teeth to mesh with the teeth on the first jaw.

38. (Withdrawn) The system of claim 36 wherein the collar includes a recessed area for receiving the clamp.

39. (Withdrawn) The system of claim 36 wherein the collar defines a distal cavity adjacent to the first opening and a proximal cavity adjacent to the second opening, wherein the distal and proximal cavities are cylindrical cavities, wherein the first hollow cavity has a diameter smaller than a diameter of the second cavity.

40. (Withdrawn) The system of claim 36 wherein the collar defines a cavity adjacent to the second opening and encircled by the clamp, wherein the first portion of the overlap area is positioned within the cavity, the connector further comprising a collet within the cavity, wherein the collet is configured to surround at least the first portion of the overlap area of the first and second catheter, wherein the collet is more rigid than both the first and second catheters.

41. (Withdrawn) The system of claim 36 wherein the collet further surrounds a portion of the first catheter that does not overlap with the second catheter.

42. (Canceled)

**Remarks**

This is in response to the Office Action dated July 22, 2010.

Before responding to the Office Action, please take note that a Power of Attorney and a Statement Under 37 CFR 3.73(b) are attached with this Amendment.

Claims 1-20 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The examiner asserts tht the phrase "wherein each of the first and second catheters have constant wall thickness in the overlap area" added in the previous amendment finds no support in the specification.

The examiner's rejection is submitted to be without merit insofar as Figs. 4 and 5 clearly show that the tubing 60 and the delivery catheter 36 each have constant wall thickness in the overlap area 100. It is well settled that drawings originally filed with the application may be used to provide the "written description of invention". To wit, the CAFC in *Vas-Catch Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), states:

We agree with the district court's conclusion that drawings alone may be sufficient to provide the "written description of the invention" required by Sec. 112, first paragraph. Several earlier cases, though not specifically framing the issue in terms of compliance with the "written description" requirement, support this conclusion. At 1564.

The court further went on to quote one of the cases per the following:

The issue here is whether there is supporting "disclosure" and it does not seem, under established procedure of long standing, approved by this court, to be of any legal significance whether the disclosure is found in the specification or in the drawings so long as it is there. *Ibid.* at 1565.

In view of the above, the examine's rejection of claims 1-20 under 35 USC 112, first paragraph, is submitted to be without merit and should be withdrawn.

Pending claims 1-20 have been rejected as being obvious under 35 USC 103(a) in view of the following: claims 1 and 3-7 under Peters (US 6,508,807); claims 1 and 3-10 under Larkin (US 4,895,570); and claims 2 and 11-20 under the combination of Larkin, Peters and Glantz (US 5,558,641).

The instant invention, as set forth in claim 1, recites that a flexible second catheter has an inner diameter sized to receive the first flexible catheter, with a portion of the first catheter being fitted within a portion of the second catheter to form an overlap area, which is surrounded by a collar, and to which collar a clamp applies a radially inward force to hold the first and second catheters together at the overlap area.

None of the cited prior art teaches any of the above. To wit, Peters discloses a female member 1 that includes a valve section 5 having slidably attached thereto a valve actuator 15. Valve section 5 has a screw threaded end 10 which is used to threadingly mate with a cap 21 of a male member 2, so that the spigot 20 at male member 2 is fitted into the frusto-conical socket 11 at valve section 5. In sum, the Peters device is a coupling device that connects two cannulas, one at the leftmost end (as shown in Fig. 1) of valve section 5 and the other connected to the rightmost end of male member 2. There is no disclosure or suggestion in Peters that the two cannulas are connected, one inside the other at respective portions thereof. As for the casing 30 shown in Figs. 4 and 5, Peters discloses that that casing 30 is used to provide additional security and protection against infection (column 3, lines 32-43). Therefore, casing 30 does not have anything to do with applying a radially inward force to the coupling device as shown in Figs. 1-3. Moreover, the cannulas that are connected by the Peters coupling device are nowhere near the casing 30, let alone overlap.

Larkin discloses a tubing connector that has an extruded tube 30 having a septum 16 that is pierced by the sharp end of a pin 20, so that a fluid communication path may be established between tube 32 and a second tube 18 that is connected to the leftmost end (from Fig. 2) of pin 20. Tube 32 is held to pin 20, more particularly the plug 34 thereof, by means of the splayed segments 26 that extend from a collet 22 (Figs. 1 and 4). The splayed segments 26 are folded over the flange 14 of tube 12 by moving the tubular locking ring 26 to the position as shown in Figs. 2 and 3. Given that pin 20 needs to “spiked into” diaphragm 16, it is not a flexible tubing. Putting it simply, the second tube 18, which is connected to the rightmost end of pin 20 does not come close to the first tube 12, which being a PVC extruded tube, is not flexible in any event. Thus, Larkins likewise fails to disclose or suggest the claimed invention.

Glantz has been cited by the examiner as disclosing a reservoir device. Applicants do not disagree with the examiner there. However, applicants do disagree with the examiner’s assertion that Fig. 13 shows a sleeve. Quite the contrary, Fig. 13 shows an insert 878 that is to be coupled to a sleeve structure 806, so that the lumens shown therein may be connected to establish fluid paths. In contrast, the “sleeve” of the instant invention is there as a guide for delivery catheter 36. In other words, for the instant invention, catheter 36 slidably moves along sleeve 68, so that it may be inserted into tubing 60, per shown in Fig. 4 of the instant specification. Nothing of the sort is disclosed or suggested in Glantz.

In view of the foregoing, applicants submit that the instant invention is patentable over the cited prior art. The examiner is therefore requested to enter the Amendment and reconsider the application.

Respectfully submitted,

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Date: October 18, 2010